SCIENCE IN FOCUS

MIEBO® (Perfluorohexyloctane) in evaporative dry eye

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KEY TAKEAWAYS

- MIEBO® (perfluorohexyloctane ophthalmic solution) forms an anti-evaporative layer at the tear-film-air interface, reducing evaporative water loss and supporting tear-film stability.
- The phase 3 GOBI and MOJAVE trials (combined n=1,219) and the 52-week extension study KALAHARI reported consistent, durable improvements in signs and symptoms of evaporative dry eye disease.
- Phase 4 and real-world evidence extends the clinical trial data into routine-practice populations; in one real-world study linked to administrative claims in the US, mean Ocular Surface Disease Index (OSDI) scores decreased from 44.0 at baseline to 29.5 at week 4 (n=60).
- In a one-month comparison with SYSTANE® PRO PF, OSDI improvements favored perfluorohexyloctane while tear film break up time improved over baseline in both groups. While authors concluded SYSTANE PRO PF was non-inferior based on OSDI, non-inferiority should not be interpreted as equivalence.

The central role of tear evaporation in dry eye disease

Excessive tear evaporation is widely recognized as a major driver of dry eye disease (DED) and is a key contributor to the condition in over 85% of cases. MIEBO® (perfluorohexyloctane ophthalmic solution) is a prescription medicine developed specifically to address the evaporative component of the disease. It is a preservative- and water-free formulation that is pH-free and has low surface tension. After instillation, it spreads rapidly across the ocular surface and forms a monolayer at the air–liquid interface of the tear film to reduce evaporative loss of the underlying aqueous layer and support tear-film stability[2].

In this Science in Focus entry, we review the evidence supporting MIEBO, including new data presented at the American Academy of Optometry 2026 meeting (AAOpt 2026) encompassing concomitant use in contact lens wear, real-world symptom data and a recent one-month comparison with a lubricating eye drop.

Pivotal evidence: GOBI, MOJAVE, and KALAHARI

The phase 3 GOBI (n=599) and MOJAVE (n=620) trials, published in 2023, evaluated perfluorohexyloctane administered four times daily for 8 weeks in adults with evaporative DED. Across

both randomized, double-masked, saline-controlled studies, treatment produced consistent improvements in the prespecified outcomes, including total and central corneal fluorescein staining and symptoms of eye dryness as early as 2 weeks. Perfluorohexyloctane was well tolerated, with low incidence of adverse events and no serious ocular adverse events reported[3,4].

The KALAHARI open-label extension followed 208 GOBI patients for an additional 52 weeks. Improvements in corneal staining and eye-dryness scores were maintained during longer-term treatment. No serious ocular adverse events occurred, and only five patients (2.4%) discontinued treatment because of an ocular adverse event[5].

Phase 4 evidence: early symptom response and cataract surgery

Two phase 4 studies have extended the evidence base reported in the pivotal clinical trials.

Early effect of perfluorohexyloctane on dry eye symptoms

A prospective, multicenter, single-arm, open-label phase 4 study in which 99 adults with DED used perfluorohexyloctane four times daily for 14 days. Perfluorohexyloctane significantly reduced patient-reported dry eye symptom severity as early as 5 and 60 minutes after the first dose, with improvements maintained through Day 14 and high treatment satisfaction. One adverse event was reported that was not considered related to treatment. These data, which establish how soon patients notice a change in their symptoms, complement the 8-week primary endpoints reported in the pivotal trials[6,7].

Perfluorohexyloctane treatment pre- and post-cataract surgery

Another prospective, multicenter, single-arm, open-label phase 4 study evaluated perfluorohexyloctane treatment before and after cataract surgery in 97 patients. Total corneal fluorescein staining decreased significantly, with corresponding improvements in eye dryness and OSDI scores, in both the pre- and post-op treatment periods. Mean OSDI scores improved from 51.9 (severe) at baseline to 11.9 (normal) at the final study visit. Two patients experienced treatment-related adverse events. Importantly, perfluorohexyloctane treatment did not impact preoperative biometry or predicted refractive error[8].

Data presented at AAOpt 2026

The American Academy of Optometry (AAOpt) annual meeting is a major forum for clinical research. In 2026, the annual meeting took place from September 30 to October 3 in Anaheim, California. Bausch + Lomb presented two studies evaluating perfluorohexyloctane in specific populations:

Contact lens wearers

A phase 4, multicenter, open-label study evaluated the safety of 104 habitual soft contact lens wearers who used MIEBO concomitantly with contact lens wear for 30 days. There was no indication of potential safety concerns during the study, while patient-reported assessments of contact lens performance and tolerability improved across the study duration. The Contact Lens Dry Eye Questionnaire-8 score decreased by 4.3 points from baseline, alongside improvements in end-of-day dryness, end-of-day discomfort, end-of-day vision, and total and comfortable contact lens wear time[9].

Real-world symptom relief with perfluorohexyloctane

In a real-world study linked to administrative claims in the US, 111 patients newly prescribed perfluorohexyloctane were asked to complete symptom surveys prior to and following initiating treatment. Among the 60 patients with week-4 data, mean OSDI score decreased from 44.0 at baseline to 29.5. These observational results are consistent with previous literature and add context to perfluorohexyloctane use in everyday care[10].

A one-month comparison *versus* a lubricating eye drop

At the same congress, Alcon presented a prospective, randomized study comparing SYSTANE® PRO PF (n=122) with perfluorohexyloctane (n=134) used four times daily for one month. Adults were included based on an evaporative phenotype and an OSDI score of 23–50[11]. Signs, including tear breakup time (TBUT) and meibomian gland function (assessed with a novel score), and symptoms, including OSDI and multiple symptom-specific visual analog scale (VAS) measures, were analyzed. The objective was to establish non-inferiority of SYSTANE PRO PF to perfluorohexyloctane based on the between-group difference in OSDI change from baseline.

Neither treatment produced a clear change in the Meibomian Gland Composite Score. TBUT improved in both groups, with numerically greater improvement with perfluorohexyloctane. All symptom measures also improved in both groups over one month. Mean OSDI decreased from 36.5 to 22.5 with perfluorohexyloctane and from 36.4 to 26.3 with SYSTANE PRO PF; significantly greater improvements in OSDI of ~3 points were observed for perfluorohexyloctane at 2 weeks and 1 month. The authors concluded that SYSTANE PRO PF was non-inferior to perfluorohexyloctane on OSDI and reported that the between-group differences did not reach their stated threshold for clinical meaningfulness (7.3 OSDI points).

However, several aspects of the study design are important when interpreting these conclusions.

1) **Patient population**: Enrollment was restricted to patients with baseline OSDI scores of 23–50; mean baseline OSDI in the perfluorohexyloctane arm was 36.5. In GOBI and MOJAVE, enrollment encompassed patients with baseline OSDI of 23-100 and mean baseline OSDI across studies was 54.6. Therefore, findings cannot be extrapolated to patients with greater symptom burden where perfluorohexyloctane has consistently shown clinically meaningful benefit in both signs and symptoms over saline control.
2) The head-to-head comparison covers a **narrow range of timepoints**. In contrast, MIEBO has demonstrated efficacy at eight weeks [3,4], through an additional 52 weeks [5], and as early as 5 and 60 minutes post-instillation[6,7]. The comparison versus SYSTANE PRO PF cannot speak to either early onset of symptom relief or longer-term durability.
3) The clinical basis for the 7.3-point **OSDI threshold is not explained**. The threshold is used both as the non-inferiority margin and to support the interpretation that the between-treatment difference is not clinically meaningful, yet its source and applicability in this population are not reported.
4) **A conclusion of non-inferiority should not be interpreted as equivalence**. Non-inferiority establishes that the test treatment was not shown to be worse than the comparator by more than the prespecified margin; it does not demonstrate that the treatments have the same clinical effect or are interchangeable. Interpretation therefore depends critically on the choice and clinical justification of the non-inferiority margin.

Overall, the Alcon study provides comparative data for a selected population over one month; however, its findings should not be interpreted as establishing equivalence between the products or as representing the full population and duration over which MIEBO has demonstrated efficacy. Of note, the two products belong to different categories. SYSTANE PRO PF is an over-the-counter lubricant marketed under the FDA ophthalmic drug monograph, with propylene glycol as the active ingredient. In contrast, MIEBO is a prescription drug and its FDA approval was supported by efficacy demonstrated on both signs and symptoms of dry eye disease.

Summary

Excessive evaporation is a prevalent and clinically important mechanism in DED. MIEBO directly targets tear evaporation with evidence spanning replicated phase 3 efficacy data, 52-week extension data, early symptom response, real-world use, contact lens wear, and the perioperative setting. Treatment decisions

in DED should consider the underlying disease mechanism together with the totality of available evidence.

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Authors' disclosures

Article authored and reviewed by Bausch + Lomb Global Medical and Scientific Affairs. Product availability and brand name may vary by region.